PACE Medical, Inc.

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January 14, 2000

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Gentlemen:

Enclosed with this letter are four copies of a Citizen Petition filed pursuant to the requirements of 21 CFR Part 898.14 and 21 CFR Part 10.30.

Questions concerning this petition or any of its attachments may be directed to the undersigned at the main address of Pace Medical, Inc. by mail or by telephone at (781) 890-5656. Thank you .

Very truly yours,

Robert C. Mace, Manager
Quality Assurance and Regulatory Affairs

Encl.

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391 Totten Pond Road, Waltham, MA 02451 USA - Telephone: (781) 890-5656 / Fax: (781) 890-4894

January 14, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under 21 CFR §10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to amend a regulation, or take or refrain from taking any other form of administrative action.

A. Action Requested

1) With respect to 21 CFR Part 898[1], "Performance Standard For Electrode Lead Wires And Patient Cables", to amend §898.11, entitled Applicability, which states as follows: "Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in §898.12." The proposed amended §898.11 shall read, "Electrode lead wires and patient cables intended for use with a medical device under circumstances which do not involve the immediate supervision of a physician shall be subject to the performance standard set forth in §898.12. Electrode lead wires and patient cables intended for use with a medical device under the immediate supervision of a physician shall be exempt from the requirements of Part 898." Or, in the alternative,

2) We request an exemption or variance for the Model 4220 Sterile Disposable Surgical Extension Cable, a Class II medical device, further identified and described by 510(k) number K913134, a copy of which with up-dated labeling is appended[2].

B. Statement of Grounds

Pace Medical, Inc. is a manufacturer of temporary cardiac pacemakers and related accessory products, one of which is the Model 4220, an inexpensive, sterile, disposable extension cable sold for use with devices generically called Pacing System Analyzers. The Pace Medical Model 4800 Pacing Analyzer is one such device. These are typically Class II / III devices. Pacing analyzers are much like temporary cardiac pacemakers and powered by batteries, not line power. They are used exclusively during the implant of a permanent cardiac pacing system or at pacing system revisions, primarily to assess the integrity and pacing characteristics of the pacing electrode(s). Such procedures are undertaken by a licensed physician or performed under his immediate supervision.

The Model 4220 sterile, disposable extension cables are used to bridge the gap between a non-sterile, remotely-situated pacing analyzer and the connector pins of the implanted leads within the sterile field. The procedures are typically performed in a cath lab, special procedures room or operating room. The disposable cables are preferentially used instead of the re-usable cables provided as an accessory of an analyzer to eliminate the need for post-procedure cleaning and re-sterilization processes which are both time-consuming and costly. The disposable cables, like all such disposable products, save staff time, resources, and enhance safety.

It is precisely because these devices are inexpensive, satisfying the requirement for an economically efficient alternative to the re-usable/re-sterilizable cables, that the pricing of disposable cables is also very sensitive to materials and process costs. The cables are a pair of stranded copper wire conductors insulated with PVC, having insulated alligator clips at one end and universal male pin connectors at the other. They are eight (8) feet in length, and bear labeling to assist with polarity verification, (+) or (-). Labels for channel identification, atrial or ventricular, are provided for physician application, if desired. Cables are individually packaged and sterilized by a validated gamma irradiation process. The connector pins plug into the pacing analyzer and the alligator clips grasp the connector pins of the implantable pacing lead. When the procedure is finished, the cables are disposed of with the other contaminated, disposable materials.

The connecting means of these cables are necessarily unsophisticated. They must be inexpensive and compatible with devices of different manufacture which have connectors that accept 2mm male pins. As for the implantable pacing leads, all are of designs which allow the shielded alligator clips to establish electrically satisfactory, temporary connections for testing purposes. No other cable design is capable of satisfying these fundamental requirements.

At the present time, there are an estimated 250,000 primary pacemaker implants performed annually in the United States. Of these, 60% are dual-chamber devices in which two pacing leads are used. The remaining 40% are single-chamber systems in which one pacing lead is used. The utilization rate of disposable extension cables with these procedures is estimated at more than 80%. Currently, the hospital cost of

sterile, disposable extension cables is typically $20.00 each. Thus, the present estimated market for the cables is about $4 million annually. The vast majority of this is reimbursed by third party insurers, principally by Medicare, following its mark-up at the hospital's standard rate. If a design change were possible, the cost of the change would be extremely important. Any significant increase in the design complexity of this product will have an adverse effect on hospital cost, cause a corresponding increase in insurance reimbursements, and undermine the inherent safety associated with universal connectivity of cables associated with cardiac pacing procedures.

Pace Medical believes that the broad scope of the Performance Standard for Electrode Lead Wires and Patient Cables is such, in some instances, as to raise the potential for creating unnecessary risks, as well as expenses for individuals and the healthcare system without a compensatory beneficial effect, particularly with respect to patient safety. That may be specifically the case where cardiac pacing applications are concerned. Since cardiac pacing became a well-accepted medical therapy in the early 1970s, its safe application has relied upon pacemakers and electrode systems which were designed around the standard of a universally compatible male pin. Recently, however, we have seen the appearance on the market of new temporary cardiac pacemakers with connectors and compatible patient cables that are used in no other medical application[3] and on no other cardiac pacemaker. The manufacturer of those devices, Medtronic, seemingly wary of the implications of this departure from the traditional connecting means undertaken in order to be in compliance with the Performance Standard, provided non-secure male pin connector sites on those devices for use in an emergency. Had that not been done, the pacemaker could be left

incapable of performing its life-saving function in the absence of its unique extension cable. So, although these pacemakers no longer have a secure male pin compatible connector, and the extension cables no longer have male pins, both still connect to heart wires and male pins from temporary cardiac pacing electrodes. That means of connection is still essential if one needs to connect to a heart wire, as Medtronic successfully argued in its request for an exemption for the heart wire[4], one of the most commonly used cardiac pacing leads. Thus, users must now be sure they not only have the right cardiac pacemaker, but also the right extension cable to connect to the right kind of pacing lead termination.

The Model 4220 disposable cables and those of the re-usable type which have been similarly used for over thirty years have no history of the inappropriate use cited in FDA Director Burlington's Safety Alert to hospital administrators, et al, dated September 3, 1993 which represented the FDA's initial action on this issue directed at apnea monitors[5]. In a second action taken on December 28, 1993, Director Burlington extended the warning to "all other devices that may use electrode lead wires with unprotected pins." Nevertheless, the list of examples cited were exclusively surface electrode devices which may have uses in other than the traditional hospital setting[6]. Additional detailed background information is provided in Part I of the FDA's subsequent Proposed Performance Standard published in the Federal Register on June 21, 1995 which was further expanded upon with the publication of the Final Rule on May 9, 1997 in Vol. 62, No. 90, pages 25477 to 25479[7].

As a specific issue, devices used by patients themselves or by minimally trained individuals acting on their own without immediate medical supervision should be

designed to conform to safety standards which may transcend those required for devices in professional use. Thus, the original scope of the FDA action, specifically on cables used by patients or minimally trained individuals in association with line powered medical devices, was as much reasonable and responsible as it was timely. However, the expanded argument that the demonstrated hazard rose to a level mandating universal applicability is less compelling, particularly given the paucity of data supporting the claim of a safety hazard in professional use.

The FDA's Particular Standard with universal applicability is based on a subclause of a voluntary standard, IEC 601-1, Amendment 1, subclause 56.3(c)[8], provisions of which can be and are waived in Europe based on contrary arguments identifying: 1) broader safety concerns and/or 2) an absence of historical data demonstrating that a safety hazard exists with designs as they are. That is the case with the Model 4220 which bears the CE mark, and whose sale in Europe is approved. The European regulatory scheme acknowledges the existence of valid exceptions, and allows for those within the framework of the "Medical Device Directive" (Council Directive 93/42/EEC; and Annex I thereto).

The sterile, disposable cables that are the subject of this petition are of a type that is beyond the reasonable scope of the FDA's paramount safety concern which is, most basically, cables that connect to or are in some manner used in conjunction with line-powered medical devices, likely to be used by poorly-trained personnel or patients themselves. Continued use of the Model 4220 sterile, disposable cables should be permitted precisely because of their universal connectivity and long history of safety in use, coupled with an improbability of misuse.

An amended §898.11, Applicability, is an appropriate way to achieve this by excluding sterile, single-use, disposable cables used under a physician's immediate medical supervision, thus drawing the proper and desirable distinction between products for professional use by or under the immediate supervision of a physician, and those in routine hospital or patient use. In the alternative, we request an exemption or variance from the requirements of 21 CFR Part 898 for the Model 4220 Sterile, Disposable, Surgical Extension Cable.

C. Environmental Impact

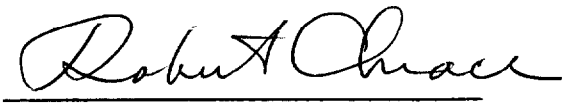
For the Model 4220 Sterile, Disposable Extension Cable (and equivalent private-labeled models) we claim exclusion from an environmental assessment. The basis of our claim can be found in 21 CFR 25.34(c). This section exempts the Model 4220 because it is the subject of an "amendment of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard."

D. Economic Impact

(To be submitted only when requested by the Commissioner following review of the petition.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition contains all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signed: 

Robert C. Mace
Pace Medical, Inc.
391 Totten Pond Road
Waltham, MA 02451

Petition References Attached

Ref. No.	Description of Document Provided
1	Copy of 21 CFR Part 898, from the Federal Register, Vol. 62, No. 90, Friday, May 9, 1997, pages 25497 and 25498.
2	Copy of Model 4220 510(k) Premarket Notification in its FDA redacted form with up-dated labeling
3	Information on Medtronic Model 5380 Pacemaker excerpted from the Model 5388 Dual Chamber Temporary Pacemaker Technical Manual, 1997.
4	MDDI Reports - "The Gray Sheet", September 14, 1998, page 17, F-D-C Reports, Inc., 1997.
5	FDA's September 3, 1993 Safety Alert
6	FDA's December 28, 1993 Health Advisory
7	Copy of Part I Background in the Final Rule on 21 CFR Part 898, from the Federal Register, Vol. 62, No. 90, Friday, May 9, 1997, pages 25477 to 25479.
8	Copy of text of IEC 601-1, subclause 56.3c), as reprinted in the "Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cables", issued on March 9, 1998, by the Director, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration.